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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,059	03/16/2004	Mark Gelfand	3659-87	1197
23117	7590	11/08/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 11/08/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/801,059

Applicant(s)

GELFAND ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 19-25 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,471,872 to Kitaevich et al.

Kitaevich discloses, in the specification and figures, the device claimed by applicant. In particular, Kitaevich discloses a renal function replacement apparatus which may perform hemofiltration, hemodialysis, or ultrafiltration (see column 2, lines 45-63). The system further comprises a blood withdrawal tube 14, blood reinfusion tube 30, filter 24, filtrate output section 64 and pump 66, a biosensor 140, and a controller 12 (see column 6, generally, column 7, lines 21-35, column 9, lines 16-25). The apparatus monitors patient parameters that may include patient cardiac output, or oxygen saturation in the blood, and that signal is compared to upper and lower values (which are considered to correspond to applicant's threshold and baseline values) and used to control the fluid pumping rates in the system (see column 3, lines 50-55, column 4, lines 28-37, column 8, lines 32-45). Kitaevich further discloses that the controller may be used in an automatic mode wherein one or more patient parameters are monitored during the hemofiltration operation (which includes an initial phase of blood filtration treatment as claimed by applicant). The controller then operates based on this real-time

patient data, considering one or more specific parameters that are stored, at least briefly, in the controller's processor in order to automatically adjust the operation of the blood filtration device (see column 4, lines 37-43).

Response to Amendment/Arguments

3. Applicant's amendment filed 12 September 2005 has been entered and considered.
4. Applicant's arguments filed 12 September 2005 have been fully considered but they are not persuasive.

Applicant argues that Kitaevich does not disclose or suggest setting a threshold value for control of blood filtration based on a baseline measurement. However, Kitaevich discloses an embodiment of the invention that includes an automatic mode that uses monitored patient parameters to control the device (see column 8, lines 60-67, column 9, lines 1-6). The controller may control operation of the device based on high and low parameter values (see column 8, lines 35-45). Kitaevich discloses that parameter data is monitored, evaluated, and responded to by the controller (see column 9, lines 36-45), indicating that it is capable of setting a baseline and threshold value based on measured patient parameters and controlling the device based on those parameters. Therefore, the Kitaevich device has a control algorithm that controls filtration based on patient parameters, as claimed by applicant.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie Deak
Patent Examiner
Art Unit 3761
1 November 2005


PATRICIA BIANCO
PRIMARY EXAMINER

11/04/05